REMARKS

A favorable reconsideration of this application is respectfully requested in view of the foregoing amendments and the following remarks.

Claims 1-25 were presented for examination, and Claims 1-9, 13, 14, 16-21 and 26-31 are now present in the case.

Claim 10 has been cancelled and re-written in more acceptable form as "new" Claim 26.

Claims 11 and 12 have been cancelled and replaced by "new" Claim 27.

Claims 15 and 25 have been cancelled without replacement.

Claim 22 has been cancelled and re-written in more acceptable form as "new" Claim 28.

Claims 23 and 24 have been cancelled and replaced by "new" Claim 29.

Claims 1-9, 13, 14 and 16-21 have been amended to explicitly reflect the fact that "crystal modification" was intended by the term "Modification" which appeared in the "original" claims and those added by the Preliminary Amendment which accompanied the "national phase" transmittal papers.

Claims 30 and 31, which are directed to preferred embodiments regarding crystal modification A', have been added.

As to the Examiner's comment that this case does not contain an Abstract, enclosed herewith is a copy of Page 19 which contains an Abstract of the invention.

The Examiner has rejected Claims 11, 12, 23 and 24 under 35 USC 101 and 35 USC 112 as being directed to "non-statutory" subject matter. In view of the fact that Claims 11 and 12 have been cancelled and replaced by "new" Claim 27, and Claims 23 and 24 have been cancelled and replaced by "new" Claim 29, this rejection is believed to have been overcome.

In addition, the Examiner has rejected all of the claims under the second paragraph of 35 USC 112 as being "indefinite" for various reasons which will be commented on in the order that they appear in the Office Action as follows:

1) The amendments to Claims 1-9, 13, 14 and 16-21 are believed to have overcome this portion of the rejection.

2) and 3) The cancellation of Claims 15 and 25 without replacement and the re-writing of Claims 10 and 22 as "new" Claims 26 and 28, respectively, are believed to have overcome these portions of the rejection.

4) Applicants do not agree that the expression "essentially pure form" is meaningless. The expression is intended to mean "essentially free of any other polymorphic forms". In this connection, the Examiner's attention is respectfully directed to the fourth complete paragraph on Page 10 of the instant specification.

5) Applicants do not agree that the phrase "but his defects in the crystal lattice" in Claims 7 and 16-20 renders said claims indefinite and their scopes unascertainable. It is clear from a reading of the specification that the phrase refers to "smaller line spacings", when compared to crystal modification A, as detected by X-ray analysis. In this connection, the Examiner's attention is respectfully directed to the third paragraph on Page 2 of the instant specification.

6) Applicants do not agree that Claim 1 fails to claim what is intended. Claim 1 is intended to claim a specific crystalline form of the compound 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4-carboxamide, viz., crystal modification A, and characterizes said crystalline form with sufficient particularity. As to the other crystalline form, viz., crystal modification A', it is identical to crystal modification A, save for smaller line spacings as detected by X-ray analysis (see the discussion in 5) above). In any event, since it is Applicants' belief that the scope of Claim 1 embraces a crystalline form, with and without defects in its crystal lattice, Claim 7 as well as other claims which depend or ultimately depend on Claim 1, are properly dependent.

7) The cancellation of Claims 12 and 24 is believed to have overcome this portion of the rejection.

In view of the foregoing, the Examiner is respectfully requested to reconsider the rejection under the second paragraph of 35 USC 112 and withdraw it.

Turning to the "prior art" rejections, the Examiner has rejected Claims 1-25 under 35 USC 102(a), (b), (e) and/or (f) as being anticipated by Meier I (European Patent 199,262) and Meier II (USP 4,789,680), the latter of which is the U.S. equivalent of the European patent. It is the Examiner's contention that since Example 4 of Meier I and Example 35 of Meier II disclose a crystalline form of the compound 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4-carboxamide from ethanol, said examples anticipate all of the instant claims. In this connection, the Examiner relies on certain case law in an effort to support her position. Applicants respectfully disagree with the Examiner's conclusion.

Although Applicants agree with the propositions set forth in the case law relied upon by the Examiner, it is Applicants' belief that they are inapplicable to the present fact situation. Quite simply, the Meier I and Meier II references are devoid of any mention that the compound 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4-carboxamide can exist in different crystalline forms, let alone the specific crystalline forms to which the instant claims are limited. Moreover, the instantly claimed crystalline forms are characterized by characteristic lines at interplanar spacings as determined by means of an X-ray powder pattern. Accordingly, neither the teachings of Meier I nor the teachings of Meier II anticipate any of the instant claims since each and every element of the instantly claimed invention is not disclosed by either the Meier I or Meier II references. See, in this connection, *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 91 (Fed. Cir. 1986), *cert. denied*, 107 S. Ct. 1606 (1987) ("every element of the claimed invention must be identically shown in a single reference").

In view of the foregoing, the Examiner is respectfully requested to reconsider the 35 USC 102(a), (b), (e) and/or (f) rejection and withdraw it.

The Examiner has also rejected Claims 1-25 under 35 USC 103 as being unpatentable over Meier I and Meier II (as identified above) in view of Munzel I (Progress in Drug Research, Vol. 10, pgs. 227-230, 1966) and Munzel II (Progress in Drug Research, Vol. 14, pgs. 309-321, 1970). It is the Examiner's contention that since the Meier references disclose a crystalline form of the compound 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4-carboxamide, save for the lines with interplanar spacings of the X-ray powder pattern of said form or any other characterizing parameters, and since the Munzel references teach that compounds can exist in different

polymorphic forms which retain the activity of the compounds, the instantly claimed crystalline forms would have been prima facie obvious to one skilled in the art from the combined teachings of the references. Applicants respectfully disagree and, in view of the following arguments, believe that the 35 USC 103 rejection is significantly defective and should be withdrawn.

Applicants readily acknowledge that Example 4 of Meier I and Example 35 of Meier II have the same chemical formula as the compound of Claims 1 and 7, the scopes of which are directed to two different crystalline forms of said compound. However, as the court stated in In re Cofer, 148 USPQ 57: "a new crystalline form of a compound would not be obvious absent evidence that the prior art suggests the particular structure or form of the compound and a suitable method of obtaining that form or structure". Accordingly, the salient question to be asked is whether the Meier references relied upon by the Examiner satisfy the strictures set forth in the Cofer decision supra? It is quite clear that one can only answer this question in the negative. Thus, no more than a cursory review of the Meier references reveals the fact that they are silent with regard to even a hint of a recognition that the specific compound alluded to above can exist in different crystalline forms, let alone contains any suggestion that different crystalline forms could or should be made or how any of the crystalline forms can be obtained. This, Applicants respectfully submit, is a critical deficiency of the Meier references. Without an obvious method of making Applicants' claimed crystalline forms, they cannot be obvious under 35 USC 103 (see, in this connection, In re Hoeksema, 58 USPQ 596). Applicants respectfully submit that different crystalline forms of a compound are not inherent or structurally obvious unless there is a clear teaching or some chemical theory which supports this conclusion (see, in this connection, In re Grose, 201 USPQ 57). In the instant case, there is no clear teaching or chemical theory which would render either of Applicants' claimed crystalline forms and the method of obtaining them prima facie obvious.

Moreover, there is nothing in the Munzel I or Munzel II references which cures the deficiency of the Meier references relied upon by the Examiner. Admittedly, the Munzel references teach that compounds can exist in different polymorphic forms. However, this represents no more than what is already known in the prior art and, accordingly, the combined teachings of the Munzel and Meier references do not clearly suggest the existence of Applicants' claimed crystalline forms and certainly nothing which would suggest how they can be obtained. At best, the combined teachings of the Munzel and Meier references represent an "invitation to experiment" which is insufficient under 35 USC 103. To wit, although the syntheses described in Example 4 of Meier I and Example 35 of Meier II results in the obtainment of 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4-carboxamide in solid form, the description is devoid of any mention of any crystal modification or mixture thereof. In

fact, upon reproducing the examples, one skilled in the art would still be unaware of the existence of crystalline forms or how they can be obtained since the crystallization conditions (e.g., concentration, quality of the solvent, quality of the crude product, temperatures, type of crystallization such as seeding, change in temperatures, etc.) are absent. In addition, from the melting point set forth in said examples, no definitive conclusion can be drawn that any crystalline form was present at room temperature since, by heating, a transformation can take place. Therefore, the mere indication of the temperature does not allow for any characterization of the solid product obtained. Still further, it is not even possible to presume which crystalline form has actually melted.

In conclusion, there must be a suggestion or teaching in the prior art that the "new" crystalline forms discovered by the Applicants could or should be made, whether by manipulation of the prior art process being relied upon or by some other process. Clearly, there is nothing in the combined teachings of the Meier and Munzel references or any other prior art which would suggest or teach that crystalline forms of the compound 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4-carboxamide exist and that they could or should be made. Nor, more importantly, is there anything in the combined teachings of the Meier and Munzel references or any other prior art which would suggest or teach a method of making Applicants' claimed crystalline forms.

In view of the foregoing, it is clear that Applicants' claimed crystalline forms are unobvious and patentable over the combined teachings of the Meier and Munzel references. Accordingly, reconsideration and withdrawal of the 35 USC 103 rejection is respectfully requested.

Moreover, the Examiner has rejected Claims 1-25 under the judicially created doctrine of "obviousness-type double patenting" as being unpatentable over Claims 1-10, 14 and 20 of USP 4,789,680 (referred to above and hereinafter as Meier II) in view of Munzel I and II (as identified above). It is the Examiner's contention that since Meier II discloses a crystalline form of the compound 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4-carboxamide and since the Munzel references teach that compounds can exist in different polymorphic forms, the instant claims are not patentably distinct over certain of the claims in Meier II. Again, Applicants respectfully disagree with the Examiner's contention and her conclusion of "obviousness".

The deficiencies of the combined teachings of Meier II and the Munzel references relative to the instant claims has been indicated above regarding the previous rejection and, accordingly, all of the foregoing arguments apply.

In short, there is nothing in the combined teachings of the Meier II and the Munzel references which would suggest or teach that crystalline forms of the compound 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4-carboxamide exist and that they could or should be made. Nor, more importantly, is there anything in the combined teachings of the Meier II and Munzel references which would suggest or teach a method of making Applicants' claimed crystalline forms.

In view of the foregoing, it is clear that Applicants' claimed crystalline forms are unobvious and patentable over the combined teachings of the Meier II and Munzel references. Accordingly, reconsideration and withdrawal of the "obviousness-type double patenting" rejection is respectfully requested.

Furthermore, the Examiner has rejected Claims 1-25 under the judicially created doctrine of "obviousness-type double patenting" as being unpatentable over Claims 1-13, 17 and 21-24 of copending U.S. Application No. 09/129,330 in view of Munzel I and II. It is the Examiner's contention that since copending U.S. Application No. 09/129,330 discloses a crystalline form of the compound 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4-carboxamide, viz., crystal modification B, and since the Munzel references teach that compounds can exist in different polymorphic forms, the instant claims are not patentably distinct over certain of the claims in copending U.S. Application No. 09/129,330. Once again, Applicants disagree with the Examiner's contention and her conclusion of "obviousness".

Admittedly, copending U.S. Application No. 09/129,330 claims crystal modification B of the compound 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4-carboxamide, as noted by the Examiner and, in fact, crystal modification C of said compound and additionally mentions the existence of crystal modifications A and A', i.e., the two crystalline forms to which the instant claims are directed. However, since copending U.S. Application No. 09/129,330 is silent with regard to any teaching as to how the specific crystalline forms of the instant claims can be prepared and since the Munzel references do not cure this defect, Applicants respectfully submit that the combined teachings of copending U.S. Application No. 09/129,330 and the Munzel references do not render any of the instant claims prima facie obvious. In any event, Applicants respectfully request that the Examiner hold this rejection in abeyance until such time that one or more claims of copending U.S. Application No. 09/129,330 are deemed to be allowable.

Applicants acknowledge the Examiner's indication that "formal" drawings will be required when the instant application is allowed.

All of the rejections of record having been overcome, the instant application is deemed to be in condition for allowance, and an early notice to that effect is earnestly solicited.

Although six "new" claims were added by this Amendment, eight claims were cancelled. In any event, since neither the total number of claims nor the total number of independent claims now present in the case exceeds the highest total previously paid for, no additional fee is necessitated by the added claims.

Respectfully submitted,

Novartis Pharmaceuticals Corporation
Patent and Trademark Dept.
564 Morris Avenue
Summit, NJ 07901-1027
(908) 522-6921

Joseph J. Borovian
Agent for Applicants
Reg. No. 26,631

JJB:mjl

Encls.: Copy of Abstract Page 19
Postcard

Date: September 1, 2000